

### **REMARKS**

Claims 1-31 are now pending in the above-referenced application. Applicants have amended claims 1 and 13 of the subject application without prejudice. Claims 3, 4, 5, 7, 8, and 20-30 have been withdrawn as being drawn to non-elected subject matter. Although the Office indicates that claim 6 is withdrawn, Applicants respectfully request that claim 6 be rejoined as claim 6 reads on the elected species. Applicants reserve the right to pursue the subject matter of the canceled claims in one or more divisional applications.

No new matter is added.

### **Information Disclosure Statement**

The Examiner is thanked for considering the March 11, 2004, September 17, 2004 and January 9, 2008 information disclosure statement. The Office has indicated that crossed-out references were not considered because copies were not provided. Submitted with this response is a supplemental Information Disclosure Statement and PTO-1449 form with copies of the crossed-out references where appropriate.

### **Claim Objections**

Claims 1, 2, 5, 9-11 and 31 were objected for allegedly containing non-elected subject matter. In addition, claim 13 is objected because the claims are not written in proper Markush format. Further, claims 1 and 13 were object to for not being in proper alternative form.

Applicants respectfully assert that claims 1, 2, 5, 9-11 and 31 should be considered as reciting elected subject matter as the elected species falls within the claims scope. Further, Applicants respectfully assert that the full scope of the claims comply with the written description requirement and are enabled for all the reasons provided in sections I and II below.

Applicants further respectfully submit the amendments herein overcome the remaining objections.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the claim objections.

### **I. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 1, 2, 5, 9-11 and 31 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In general, the Office asserts that the claimed subject matter lacks written description because "(i) substantial structural variation exists in the genus/subgenus embraced by claims 1, 2, 5, 9-11, 13-19 and 31; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenus claimed; (iii) common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art." *Office Action*, at 7. Applicants respectfully traverse, and point out that possession of the invention is properly evaluated based on Applicants' own written description of the inventive matter which was included in the specification as filed. M.P.E.P. § 2163.01.

Criteria established in the M.P.E.P. explain that the test for sufficiency of support in

an application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter. M.P.E.P. § 2163.02. Possession may be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. M.P.E.P. § 2163.

Applicants have complied with this legal criterion by providing a specification having the chemical formulas of the core structure of compounds that are the subject matter of the pending independent claims (see original specification as filed p. 2.). Further, the specification describes chemical substituents that branch from these core formulas that are recited by the pending independent claims. (see original specification pp. 5-17). Also, the specification provides definitions of each generic chemical substituent used in the claims and examples of actual compounds that exemplify these generic substituents. (see original specification pp. 17-23). In addition, the specification as filed provides representative compounds that exemplify the pending independent claims. (see original specification on pp. 12-16). Most importantly, the specification as filed shows 101 examples including structures of representative compounds and description of their preparation that exemplify the pending independent claims. Furthermore, the specification indicates further functional characteristics of the claimed compounds, including having a minimum inhibition concentration of 128 µg/ml or less against at least one of the claimed organisms. Finally, the specification provides assays and efficacy test data for the representative compounds that exemplify the compounds of formula I. (see examples A-D, original specification on pp. 151-155). One of ordinary skill in the art of chemical synthesis, reading the application at the time it was filed, would readily have understood that Applicants were in possession of sufficient examples of the subject matter that exemplify the pending independent claims such that Applicants were fully in possession of this claim. Accordingly, Applicants submit that the specification contains disclosure of relevant identifying characteristics of the claimed invention, including both definitive structural features and functional characteristics, sufficient to show that the Applicants were in position of the claimed invention.

Therefore, Applicants assert that the ordinarily skilled artisan and the public, reading the specification at the time the application was filed, would have been made aware of the metes and bounds of the pending independent claims of the current application, and that the pending independent claims convey a description of the compounds with more than reasonable clarity to those skilled in the art.

The Office, however, indicates that Applicants' claims should be limited to the "the compounds reduced to practice". *Office Action*, at 7 However, it is a well-established principle that claims are not limited to the disclosed embodiments. As provided in *Ex parte Obukowicz* "[i]t is well settled that patent applicants are not required to disclose every species encompass beyond their claims, even in an unpredictable art." 27 USPQ2d 1063, 1067(Bd. Pat. App. & Interf. 1992).

The Office also asserts that the specification does not provide "common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art." *Office Action*, at 7. However, Applicants again are not required to provide a structure activity analysis to possess written description for the pending claims. Applicants have disclosed numerous specific examples of compounds within the scope of the claims and have provided information about the activity of the claimed compounds.

Applicants submit that one of ordinary skill would readily determine that Applicants possessed the invention of the pending claims at the time the application was filed based on the above description and examples.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the written description rejection of claims 1, 2, 5, 9-11 and 31 under 35 U.S.C. § 112, first paragraph.

## **II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 1, 2, 5, 9-11, 13-19 and 31 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention. Specifically, the Examiner concedes that the specification is enabling for "compounds that have adequate written description", but alleges that it "is not enabling for using compounds that are not supported by the disclosure." *Office Action*, at 8.

Applicants, however, respectfully traverse the Office's rejection on the grounds that as provided in section I, the full scope of the claims is properly supported by the specification. Hence, Applicants respectfully submit that the pending claims are fully enabled by the specification. Applicants now address each of the Wands factors which support a finding that the pending claims are fully enabled.

### **The Nature of the Invention**

The nature of the invention is a compound of Formula I, II or III having a minimum inhibition concentration of 128 µg/ml or less against at least one of the claimed organisms.

### **The Breadth of the Claims**

The Office alleges that the "[c]laims drawn to compounds that do not have written description support" are allegedly too broad. (*Office Action* at 8.). Applicants, however, respectfully traverse the Office's rejection on the grounds that as provided in section I the full scope of the claims are properly supported by the specification and comply with the written description requirement.

### **The State of the Prior Art, Predictability, Guidance and Working Examples**

Applicants respectfully submit that the working examples and guidance provided in the description in the specification is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

The Court of Customs and Patent Appeals (C.C.P.A.), which has now been superseded by the Court of Appeals for the Federal Circuit, stated in *In re Borkowski*, 164 U.S.P.Q. 642 (C.C.P.A. 1970) that "There is no magical relationship between the number of representative

examples and the breath of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode' contemplated." *Id.* at 646. Applicants respectfully submit that they have provided an enabling disclosure for the full scope of claims 1-35. The Applicants have, therefore, complied with the statutory requirements of § 112.

Applicants respectfully submit that the specification of this case contains support sufficient to enable one of ordinary skill in the art to practice the inventions of each of the pending claims. In this regard, Applicants respectfully direct the Examiner's attention to the detailed synthetic schemes that have been provided. Applicants have provided detailed synthetic schemes on pages 27, 28, 30, 32, 35, 37, and 40 that teach one of ordinary skill in the art how to make the claimed compounds of the present invention. Moreover, Applicants have provided a detailed written description on pages 27-40 of the reaction steps employed in the aforementioned synthetic schemes. The specification also sets forth in detail over 100 representative examples of compounds of the claimed invention that were prepared using the disclosed synthetic schemes.

Applicants respectfully submit that one of ordinary skill in the art would be capable of making applicants' claimed compounds different from those specifically described. "*It is manifestly impractical for an applicant who discloses a generic invention to give an example of every such species.* It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it." *In re Kamal*, 398 F.2d 867, 158 U.S.P.Q. 320, 323 (C.C.P.A. 1968), quoting *In re Grimme*, 274 F.2d 949, 124 U.S.P.Q. 499, 501 (C.C.P.A. 1960) (emphasis added). An applicant need not provide a specific example of everything embraced by a broad claim. *In re Anderson*, 471 F.2d 1237, 176 U.S.P.Q. 331 (C.C.P.A. 1973).

Applicants respectfully submit that they have taught those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The law does not require Applicants to disclose an example of every claimed compound. The specification of the subject application provides sufficient detail for one of ordinary skill in the art to prepare the claimed invention. Furthermore, preparation of additional compounds is a matter of routine experimentation given that the high level of skill and knowledge in the art.

Applicants reiterate the fact that they have provided a specification that contains detailed synthetic schemes providing guidance on the preparation of the claimed compounds and also provided a large number of working examples. Applicants' disclosure coupled with the high level of skill (which the Office admits) in the art is sufficient to enable one of ordinary skill in the art to practice the claimed invention.

On page 8 of the Action the Office states that "[o]ne of ordinary skill could not predict which of the structurally diverse compounds, embraced by the claims but not exemplified/supported by the disclosure, would possess the desired activity." For the reasons that follow, Applicants respectfully disagree with the Office's position. Applicants respectfully submit that the specification of this case contains support sufficient to enable those skilled in the art to practice the inventions of each of the claims. Applicants' specification adequately discloses to one skilled in the relevant art how to make and use the claimed invention without undue

experimentation. The pharmaceutically active compounds employed in these claims are described on pages 12-16 of the specification, and methods by which such compounds can be prepared are described in detail on pages 27-40 of the specification. All the descriptions in the specification that are referred to above are written in clear and concise language using terms that are familiar to those skilled in the art.

Moreover, the specification sets forth in detail, on page 2, that the compounds of the present application inhibit LpxC and thereby possess gram negative antibacterial activity. Further, on pages 151-155 the specification sets forth *in vitro* and *in vivo* tests which can be followed to assess the activity of any compound falling within the scope of the present application. The foregoing information is sufficient to enable one skilled in the art to practice the inventions of each of the pending method claims and thus complies with the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, Applicants' disclosure (guidance and working examples) coupled with the high level of skill in the art is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

#### **Quantity of Experimentation**

The Office concludes that undue experimentation would be required to practice the invention. As mentioned above, the courts have established that additional experimentation can be performed while meeting the requirements of 35 U.S.C. § 112. Thus, the fact that additional experimentation may be required is not sufficient to suggest that the claims are not enabled. Applicants have provided adequate description in the specification to enable one of skill in the art to practice the claimed invention with merely routine experimentation.

Based on all of the *Wands* factors and consideration of the evidence as a whole, it is respectfully submitted that the patent application includes a description of the claimed invention in compliance with § 112, such that the rejection, upon reconsideration, should be withdrawn. In reconsidering whether the patent application includes an enabling disclosure of the claimed invention, the Patent Office must consider all evidence in the record (including the patent application), weighing evidence that confirms enablement against evidence that refutes enablement. See *In re Wands*, 858 F.2d at 737, 740. Accordingly, reconsideration and withdrawal of the rejection to claims 1, 2, 5, 9-11, 13-19 and 31 are respectfully requested.

**CONCLUSION**

In view of the remarks and amendments, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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